# Fetal Pillow in Women Undergoing Caesarean Section at Full Dilatation & Caesarean Section for a Failed Instrumental Delivery.

*Dissertation submitted to*

**THE TAMILNADU Dr.M.G.R. MEDICAL UNIVERSITY**

*in partial fulfillment for the award of the Degree of*

**M.D. OBSTETRICS AND GYNAECOLOGY**

**BRANCH II**

**MADRAS MEDICAL COLLEGE**
**CHENNAI**

**APRIL - 2012**

# *Certificate*

This is to certify that the dissertation titled "**FETAL PILLOW IN WOMEN UNDERGOING CAESAREAN SECTION AT FULL DILATATION & CAESAREAN SECTION FOR A FAILED INSTRUMENTAL DELIVERY"** is the bonafide work done by **Dr. S. KAVITHA** between September 2010 to August 2011 during her M.D.,O.G., course at ISO - KGH, MMC Chennai.

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# *Ethical Committee Clearance Certificate*

**INSTITUTIONAL ETHICAL COMMITTEE**
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**CERTIFICATE OF APPROVAL**

To
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Dear Dr. S. Kavitha

The Institutional Ethical Committee of Madras Medical College reviewed and discussed your application for approval of the project / proposal / clinical trail entitled **"Fetal Pillow in women undergoing Caesarean Section at Full dilatation and Caesarean Section for a Failed Instrumental Delivery" No 08092010.**

The following members of Ethical committee were present in the meeting held on 14.09.2010 conducted at Madras Medical College, Chennai -3.

1. Prof. S.K. Rajan, MD -- Chairperson
2. Prof. J. Mohanasundaram, MD,Ph.D,DNB -- Deputy Chairman
   Dean, Madras Medical College, Chennai -3
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    Social Scientist

**We approve the proposal to be conducted in its presented form.**

Sd /. Chairman & Other Members

The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information / informed consent and asks to be provided a copy of the final report

Member Secretary, Ethics Committee

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# *Introduction*

# 1 *Introductions*

CESAREAN section is commonly perceived as a simple alternative to difficult vaginal birth. This cliche is used to explain the continuous increase in cesarean section rates observed in developed as well as in resource poor countries and even in countries with a traditional conservative approach to child birth.

Incidence of cesarean section (CS) has risen steadily in the last two decades, in most developed countries the incidence is now around 25%. The high rate of CS is now regarded as a major public health problem. This concern is well placed, because it is likely that the upward trend will continue.

The reasons for the increased rates are complex: the safety of the operation leading to complacency, relative lack of skill of the younger obstetricians, fear of litigation and the pressure from the consumer has also been cited.

There has been a decrease in the rates of operative vaginal deliveries with a corresponding increase in CS deliveries in the second stage of labor. CS during the second stage of labor with an impacted fetal head can be technically difficult and is associated with increased risk of maternal morbidity due to major hemorrhage, trauma to the lower uterine

segment, uterine incision extension, and prolonged operative time. Delaying CS until the second stage of labor also puts the fetus an increased risk of hypoxia.

The practicing obstetrician may encounter difficulty in disengaging a deeply impacted fetal head during CS at advanced labor, a situation that may result in serious maternal and neonatal morbidity. The maneuvers to disengage the wedged head include pushing(bimanual or an assistant) the head through the vagina or alternatively, pulling the infant's feet through the uterine incision. These methods are well known to cause serious maternal and neonatal complications.

This study ,by using a novel device, FETAL PILLOW, a simple fetal disimpacting system disimpacts the wedged fetal head during CS thereby reducing complications at CS done during second stage of labor.

# *Review of Literature*

# 2 Review of Literature

**Cohen (1977)** investigated the fetal effects of second stage labor length at Beth Israel Hospital. He included 4403 term nulliparas in whom electronic fetal heart rate monitoring was performed. The neonatal mortality rate was not increased in women whose second stage labor exceeded two hours. Epidural analgesia was used commonly, this likely accounted for the large number of pregnancies with prolonged second stage.

**Menticoglou & Colleagues (1995 a,b)** challenged the prevailing dictums on the duration of the second stage. These arouse because of grave neonatal injuries associated with forceps rotation to shorten second stage labor. As a result, they allowed a longer second stage to decrease the vaginal operative delivery rate.

**Myles & Santolaya (2003)** analyzed both the maternal and neonatal consequences of prolonged second stage labor in 7818 women in chicago between 1996 -1999. Maternal outcomes – Caesarean Delivery, Instrumental Delivery, Perineal Trauma, Post – Partum Hemorrhage, Chorioamnionitis increased with the duration of second stage labor. Neonatal mortality and morbidity rates were not related to the length of the second stage.

**Robertson & associates (1990)** reported significantly higher neonatal morbidity in the mid-forceps group compared with infants born by caesarean delivery.

**Wood et Al (1987)** a time dependent correlation exists between the duration of second stage labor and the indices of a fetal acidosis such as low pH, high base deficit & lactate concentrations.

**Katz et Al (1987)** showed a significant rise in umblical cord lactate concentration when the second stage lasted longer than 30 mins.

In a study of 122 women, who had a trial of mid cavity forceps or vacuum extraction in a setting with full preparation to proceed to caesarean section, **Lowe (1987)** found no significant difference in immediate neonatal or maternal morbidity compared with that of 42 women delivered for similar indications by caesarean but without such a trail of instrumentation. Conversely, neonatal morbidity was higher in 61 women who had 'unexpected' forceps or vacuum failure in which there was no prior preparation for immediate caesarean delivery.

As early as **1984, Landsman & Graber** suggested that with the greater use of caesarean section and the sharp reduction in rotational and mid forceps deliveries, procedures to disengage an impacted fetal head might have an increasingly important role in the obstetric armamentarium.

In a retrospective study from Canada, **Allen et Al** found that women undergoing caesarean section at full cervical dilatation were 2.6 times more likely to have

complications of maternal intra-operative trauma (p<.0.001). There were no differences in rates of blood transfusion, hysterectomy, wound infection, Febrile morbidity or post partum hemorrhage. A significant finding was a increased risk of perinatal asphyxia, although they did not report a high rate of encephalopathy.

**Cebekulu & Buchmann (2006)** analyzed complications associated with CS in the 2nd Stage of Labor. There were 39 cases and 39 controls. CS in the 2nd Stage of Labor took significantly longer (med 45 vs. 30 mins) and was associated with more frequent post operative pyrexia (10 vs. 2; p=0.0012). There were more neonatal admissions in the case group (17 vs. 3; p<0.001). HIE was more frequent in infants following 2nd stage CS (8vs1; p =0.013) as was subaponeurotic hemorrhage (6 vs. 0; p =0.012). Thus, CS in the 2nd stage of labor is associated with significant intra operative & neonatal morbidity. (Int. Journal of OBG).

**Towner et Al** in his study found that 2.8% of all CS performed during labor in california between 1992 – 1994 were done after a failed vacuum or forceps delivery. when compared with successful vacuum extraction, CS after a failed vacuum attempt increased the risk of intra cranial hemorrhage from 1 per 854 to 1 per 333 births and the risk of convulsions from 1 per 854 to 1 per 142 births.

**Subrata Lall Seal (2010)** evaluated the maternal & perinatal complications of CS in second stage compared with the first stage of labor in nulliparus women. There were 1702 caesarean deliveries performed in the first stage & 124 cases in the 2nd stage. C.S

deliveries performed in the 2nd stage were associated with longer operations time & increased need for blood transfusion, rates of wound infection, intra operative complications & need for transfer to ICU. Neonatal complications included significantly low Apgar score at 5 min, increased neonatal death, admissions to neonatal ICU, increased need for intubations, septicemia, neonatal seizures & fetal injury (all having $p<0.05$). Caesarean deliveries performed in the second stage of labor were associated with higher rates of maternal & neonatal complications. (American Journal of Perinatology).

**Moodley et Al (2009)** in their retrospective study carried out at a district maternity unit in Durban. There were 4654 deliveries, including 1257 CS in the study period. The CS rate was 27.2% of 617 (8.5%) emergency CS's, 53 were performed in the second stage of labor. The maternal & neonatal complication rates were low & no statistical differences were found between the patients who had second stage or those who had first stage CS, except for increased blood loss, blood – stained urine, prolonged operative time and post operative fever for second stage caesarean section.

**Murphy DG, *et AL*** assessed the operative delivery in the second stage of labour in relation to fetal morbidity, and found it more with the use of more than one instrument, more manipulation and also operative experience.

**Mc Queen & Mylrea 1977, Kadar & Romero 1983** in their studies reported no differences in fetal and / or maternal outcomes in women who had prolonged second stage of labor compared to those in whom the second stage of labor was shortened. These studies,

however, did not address long term maternal morbidity such as utero vaginal prolapse and urinary/ fecal incontinence.

**PM Gopinath et Al, Singh & Varma et Al (2008),** in their Pilot study with fetal disimpacting system in 30 women in advanced labour with deeply engaged head at the institute of Obstetrics & Gynacology and Govt. Hospital for Women and Children Chennai, INDIA – a mean elevation of 3 cm was achieved with fluid volumes of 60-120 ml. There was no device expulsion and the fetal head was delivered with ease in all women. Both the vagina and fetal head were examined carefully after the caesarean section to look for trauma and none was seen.

**Mandeep Singh (2010)** in a prospective randomized study including 28 pregnant women who underwent caesarean section at second stage, between Jan 2008 – Jan 2009 in Basildon University,UK with fetal disimpacting system. There was no Trauma to the maternal vaginal tissue or fetal head from the device use. In 24 patients (85.7%) there was no extension. The mean blood loss during the caesarean section was 700 ml. The mean fetal weight was 3.434 kg. The mean umbilical cord pH was 7.298. The FDS is safe to use and facilitates the delivery of the impacted fetal head during caesarean section at full dilatation.

# *Overview*

# 3 Overview

**"Second stage of labor has been termed the most dangerous journey a human ever undertakes."**

## *Second Stage of Labour*

Second Stage of labour begins when cervical dilatation is complete and ends with fetal delivery. The actual distance traversed by presenting fetal part during this time is approximately 6 inches.

Fetal descent largely follows complete dilatation. Moreover, the second stage incorporates many of the cardinal movements necessary for the fetus to negotiate the birth canal. Accordingly, the disproportion of the fetus and pelvis frequently becomes apparent during the second stage labor.

The Confidential Enquiry into still births and deaths in infancy and the number of medico legal overviews reinforce the dangers of second stage of labor. Ignoring abnormal CTG's or attempting instrumental delivery inappropriately in the second stage of labor are the most common causes of medical negligence. The second stage of labor reamins a controversial area and, as yet, there are no college guide line for management.

The second stage of labor itself has two phases. The first phase starts with full dilatation and ends when bearing down efforts starts. The second phase is termed expulsive.

During the expulsive phase of the second stage there is a gradual lowering of the umblical vein and artery pH, with progressive respiratory acidosis and lactic acidemia. Although uncommon, undetected intra partum asphyxia at this stage may lead to Hypoxic Ischiemic Encephalopathy in the neonate. Adverse maternal outcomes associated with prolonged second stage includes post partum hemorrhage, puerperal fever, low back ache and pelvic floor denevervation.

The median duration of the second stage is approximately 50 mins. for nulliparaous and about 20 mins. for mutliparaous, but it is highly variable. Descent of the presenting part at a rate of >= 1 cm/hr. in nulliparaous women and >=2 cm/hr. paraous women was proposed as normal progress during the second stage of labor. (Freidmanet at 1970).

## *Prolonged Second Stage of Labor*

***Def.*** **Prolonged Second Stage of Labor is defined as greater than two hours.**

This may lead to fetal hypoxia and lower APGAR scores at birth. Prolonged second stage of labor is now a recognized risk factor for pelvic floor trauma and pressure related nerve damage leading to medium and long term pelvic floor dysfunction including symptomatic utero vaginal prolapse and urinary and fecal incontinence.

The modern management of the second stage of labor will have to balance these risks against the risks and benefits of the obstetric interventions, such as episiotomy,

instrumental vaginal delivery and caesarean section which are used when the second stage labor is prolonged.

Second stage interventions are the methods to facilitate delivery of the fetus in the form of assisted vaginal delivery or by operative delivery. World wide, 10-20% of deliveries require some form of interventions and this intervention is frequently caesarean section.

## *Deeply Engaged Head at Caesarean Section*

The true incidence of caesarean section with a deeply engaged head is not known. There has been a disproportionate increase in caesarean section being performed in second stage in the last few years, probably accounts for 1/4th of all emergency caesarean section. Patients with failed instrumental delivery and caesarean section in late labor account for most of these cases. It may also be as a consequence of a deep transverse arrest, arrest in occipito posterior position and an unanticipated CPD late in labor. Relatively smaller number of caesarean section in early labor and those performed electively might also occasionally have a deeply engaged head.

The following might be some of the contributing factors:

a) Reluctance to resort to instrumental delivery, particularly rotational forceps in second stage.

b) Less stringent guidelines regarding the length of second stage and increasing use of epidural analgesia leading to prolonged second stage.

c) Higher incidence of failure of instrumental delivery.

Caesarean section in late labor or at full dilation with reduced liquor & an engaged fetal head can be a very difficult procedure, and carries a higher risk of complications both for the mother and the fetus.

The Mechanism of difficult delivery of the fetal head during caesarean section is not entirely clear.

It follows that impaction of the fetal head is a manifestation of an advanced first stage and much more likely an event of second stage. More over, impaction seems to be more likely when the second stage is unduly prolonged and frequently already exists at a stage when the clinician must decide whether to perform an instrumental delivery or a caesarean section. Sometimes, both situations co exists, as is the case with the caesarean section follows a failed instrumental delivery.

The contributing factors that potentially lead to intraoperative disengagement dystocia derive from changes in obstetrical practice. First, some cases may result from greater reluctance to perform instrumental deliveries. Indeed, the alleged potential for birth trauma related to instrumental delivery for prolonged second stage reduced the incidence of such deliveries and led to increased likelihood of cesarean sections. For example, recent USA data show a 26.1% cesarean delivery rate for 2002, the highest ever reported in the United States, and representing a 7% rise from 2001 and 14% increase from 1989. Concurrent with this rise in the cesarean delivery rate, the percentage of births delivered by either forceps or vacuum extraction has decreased since 1996, and the 2002 rate (5.9%) is 61% lower than the high of 9.5% in 1994. This concurrent increase in cesarean births and decrease in instrumental deliveries suggests that many deeply engaged fetuses that were managed in the past by either vacuum or forceps delivery are currently delivered by

cesarean section at a stage when the fetal head might already be deeply wedged in the maternal pelvis.

A second potential contributing factor is the less stringent adherence to the duration of the second stage, mainly in patients under epidural anesthesia with a reassuring continuous fetal heart rate during monitoring . Delayed maternal ‘‘pushing’’ in the second stage of labor – promoted to preserve the pelvic floor and function of the anal sphincter and pudendal nerve – has also been associated with a significantly longer duration of the second stage. It is therefore conceivable that the longer the interval of the second stage, the higher is the likelihood of fetal head impaction. Significant molding and the formation of a caput also add to wedging of the head.

A third potential contributor is the more frequent use of epidural anesthesia in current obstetrical practice. Little doubt exists that this mode of pain relief is associated with a reduced maternal urge to push and, hence, a longer second stage and increased likelihood for the fetal head to become wedged in the pelvis. It is still undetermined, however, whether relaxation of the pelvic musculature associated with epidural anesthesia leads to faulty descent and abnormal negotiation of the fetal head and how these steps of natural birthing may be involved in wedging of the fetal head.

Finally, further impaction of the fetal head may occur during trial of instrumental delivery. Here, the vacuum extractor seems to be more significant because it allows larger head diameters to be pulled into the pelvis compared with forceps. The vacuum extractor may actually pull on a large caput to the stage of ‘‘crowning’’, causing further impaction, but not an advance of the fetal head below the midpelvis. Moreover, the vacuum, per se,

may increase the size of an already existing caput, thus further increasing the likelihood of difficult disengagement.

## *The surgical problem*

In the common scenario, intraoperative disengagement dystocia occurs in a cataclysmic atmosphere. Following an apparently normal progress of labor with a normal descent pattern, and after pushing for some time, arrest of descent occurs at a rather low station. At this point, usually when a significant caput has been already formed and non-reassuring changes in fetal heart rate patterns frequently occur, the obstetrician must decide between an assisted vaginal delivery and a cesarean section. In the former case, the situation becomes even more urgent when vacuum extraction or forceps fails to deliver the head. Clearly, pulling the undeliverable head produces more wedging.

Regardless of whether an instrumental delivery was attempted, significant changes in the lower uterine segment have already occurred, obscuring the anatomical landmarks that differentiate between the vagina, cervix, and uterine body. In this context, the importance of the location of the incision is clear, because a standard incision will frequently result in extension into the broad ligament or to the vagina and bladder. If made too low, it is possible that the incision will be in the vagina rather than in the lower segment. Inadvertent vaginal incision (the so-called anterior vaginotomy) in such circumstances commonly leads to extension of the incision into the lower part of the broad ligament, profuse bleeding, and potential injury to the ureter. If, on the other hand, the incision is made too high, the presenting part of the fetus at the incision is usually the

shoulder or even the fetal chest. When the uterus is incised, it is also common to observe how the upper uterine segment forcefully embraces the fetal body. Also, the fetal spine acts as a splint in the uterus which is already contracted upon the fetus and the flexion of the fetal neck in order to lift it up to the uterine incision may not be possible.

When the surgeon introduces his hand in order to deliver the fetal head, he/she may find that the lower pole of the molded head (frequently further elongated by a large caput) is deeply impacted in the pelvis, and is in fact undeliverable.

RCOG recommends the presence of a consultant Obstetrician when ever a caesarean section is performed in the second stage of labor.

## *Complication and Facts of Seconds Stage Caesarean Section*

- **Post Partum Hemorrhage (Blood loss > 1000 ml in 20% of second stage CS).**
- **Extension of Uterine Incision (Up to 35%).**
- **Increase Length of Hospital Stay for Mother and Baby.**
- **Increased fetal morbidity (Neonatal Trauma from the failed instrumental delivery, admission to NICU).**
- **Deeply engaged head with Caput and Moulding.**
- **Thin and Stretched lower segment.**
- **Reduced or absent Liquor.**
- **Lack of space between head and pelvic cavity.**
- **Increased manipulation and excessive force to deliver the baby.**

## *Techniques Described for the Delivery of Deeply Engaged Head*

The difficulty in delivering the fetal head arises because of lack of space between the bony pelvis, pelvic soft tissues and the fetal head and the degree that the head has moulded into the pelvis. This lack of space makes it difficult for the surgeon to insert their hand to dislodge the fetal head from the pelvis. Several techniques have been reported in the literature for delivery of a deeply engaged head.

- Use of an assistant to push up the fetal head vaginally when attempts to deliver abdominally have failed. It is important that the push is only applied when the uterus is not contracting. This may lead to a significant delay in uterine incision to delivery time. It can also be associated with direct fetal trauma due to uncontrolled force used by the assistant to dislodge the head from below.

- Abdominovaginal delivery has been described by Landesman. The woman is placed in the Whitmore position (a modified lithotomy position where the thighs are moderately abducted and flexed to an angle of approximately 135 degrees relative to the trunk) and an assistant introduces their hand into the vagina to push the head up, the surgeon at the same time places an upward traction on the shoulders to help in dislodging the head.

- Breech extraction can be achieved if a high transverse incision is made or a J-shaped extension is made to the normal lower segment incision. Extension of the incision is very common with this manoeuvre.Anticipating difficulty and making a vertical incision is the ideal course of action when attempting a breech extraction.

- A prospective randomised trial reported by Fasubaa et al. suggested a lower risk of fetal and maternal injury when the fetus was delivered by a pull method as compared to the push method.

All these techniques rely on extensive experience that is often not immediately available on the labour ward. Caesarean sections are usually performed by doctors in training who are unlikely to be experienced enough to deviate from the normal techniques of performing a caesarean section. The sentinel audit report published by the Royal College of Obstetricians and Gynaecologists recommended a consultant presence whenever caesarean section is performed at full dilatation.

Anticipation of a difficult delivery at caesarean section is important.Failed instrumental delivery, occipitoposterior position, secondary arrest in labour and excessive moulding should alert the obstetrician to the possibility of this complication occurring. A careful abdominal palpation and bimanual examination to assess engagement of the head could further help to predict difficulty in delivery of the fetus by caesarean section. The simple device **FETAL PILLOW**, used in this situation prophylactically, could reduce some of the complications associated with a deeply engaged head that can lead to serious maternal and fetal morbidity. It could also be used instead of an assistant to elevate the fetal head when attempts to deliver the head during caesarean section have failed.

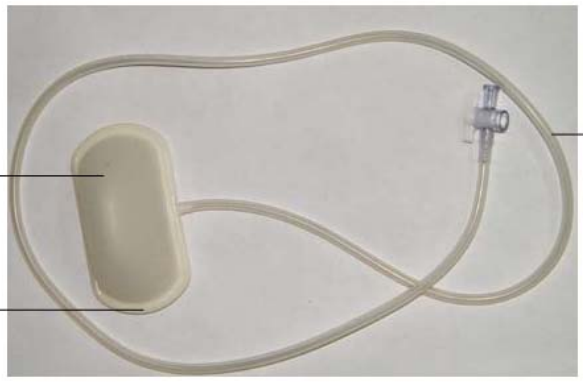
# *Fetal Pillow*

The Foetal Pillow is manufactured by Safe Obstetric Systems UK Ltd. It consists of a base plate 9.5 cm long and 4.5 cm wide, foldable along the midline of the short axis towards the superior surface, to which a balloon is attached. The balloon is attached through a connector to tube 100 cm in length that is, in turn, attached to a 60ml syringe through a two-way connector. It is inserted vaginally below the fetal head at the time of inserting a Foley catheter or after a failed attempt at an instrumental delivery. It is folded along its short axis and aligned so that the fold of the device is in anteroposterior diameter of the pelvis, and inserted using a generous amount of obstetric cream (the process is no different from inserting a ventouse cup). Once in the vagina, the device is placed posteriorly, like a ventouse cup for an occipitoposterior position. Once inserted, the woman's legs are straightened (this closes the vaginal opening and prevents the downward movement of the device when it is inflated) and the patient is prepared for caesarean section. The time taken for this manoeuvre is around 30 seconds. An assistant uses 180mls of saline to inflate the balloon using a 60mls syringe. The inflation is maintained only for a short time just before making the uterine incision.

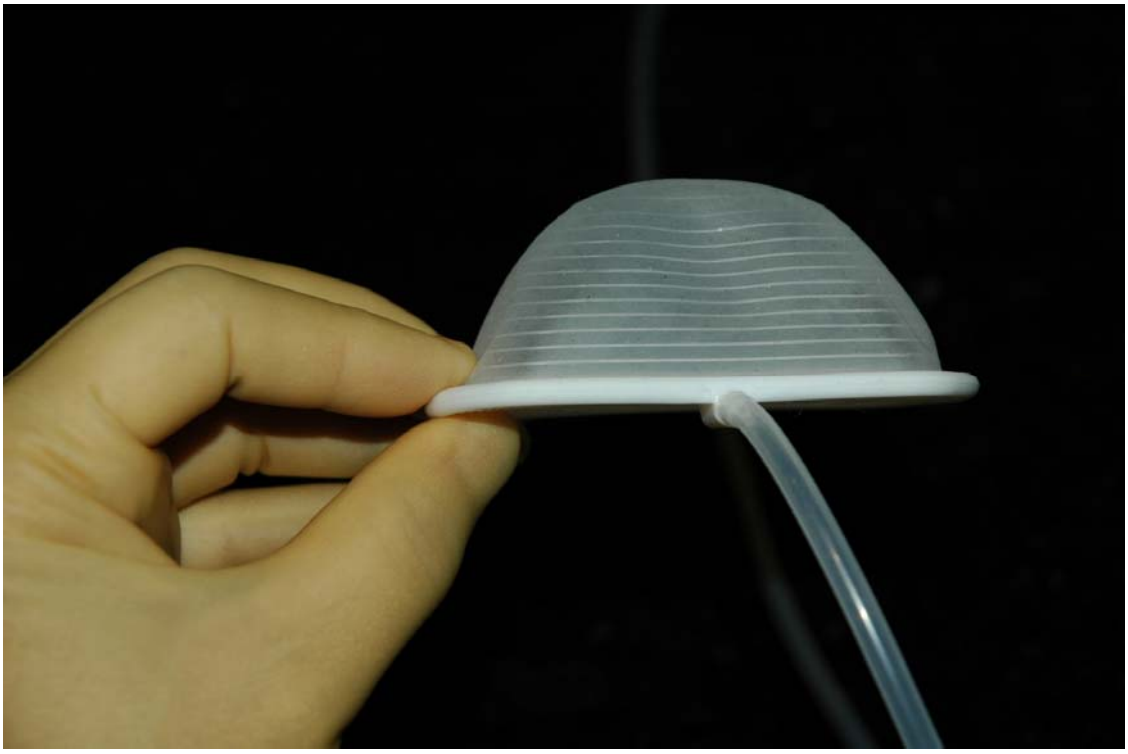
As the balloon inflates it gently elevates the fetal head 3-4cms from its position, making it easier to deliver. As soon as delivery is achieved, the balloon is deflated and can be removed: the device can be gently pulled out using the attached tubing or by hooking a finger into the base plate.

# *Fetal Pillow Device Pack*


## Fetal Pillow Device Description



## *The Fetal Pillow*



## *Inflated Fetal Pillow*

# *Aim of Study*

# 4 Aim of Study

## *Aim of this Study:*

***To evaluate fetal pillow, a non invasive technique in women undergoing second stage caesarean section, to determine its role in minimizing the maternal and neonatal morbidity.***

### *Primary objective*

- Does the Fetal Pillow improve maternal and fetal outcome in patients having a Caesarean Section in second stage.

### *Primary endpoint(s)*

- Extension of uterine incision (Hysterotomy).
- Post partum haemorrhage.

## *Secondary endpoints*

- Time taken for CS.
- Need for senior help.
- Blood transfusion.
- Length of hospital stay.
- Admission to NICU.
- Other maternal trauma.
- Direct fetal trauma.

# *Materials and Methods*

# 5 Materials & Methods

## Settings:

**The study was conducted at the Institute of Social Obstetrics & Govt. Kasturba Gandhi Hospital, Triplicane, Chennai – during the period 2010 to 2011.**

***Study Group:***

The study group includes 30 patients undergoing caesarean section with singleton pregnancy in cephalic presentation for failed forceps delivery, failed ventouse (vacuum) delivery,8-10 cm of cervical dilatation with failed progress of labor, deep transverse arrest, excessive moulding of fetal head at Institute of social obstetrics and Govt. Kasturba Gandhi Hospital and evaluate the use of fetal pillow in these group of patients. Compared simultaneously with the control group consisting of 30 patients who underwent second stage caesarean section but not opted for the device.

## Design of the Study:

**Prospective randomized controlled trial.**

## Period of the Study:

**One Year.**

## *Inclusion Criteria:*

- **Age 18 - 35yrs.**
- **Willing and able to give informed consent.**
- **Failed forceps delivery.**
- **Failed ventouse delivery.**
- **Second stage CS.**
- **Deep transverse arrest.**
- **Excessive Moulding of Fetal Head.**

## *Exclusion Criteria:*

- **Age less than 18 yrs and above 35 yrs.**
- **Unwilling or unable to give informed consent.**
- **Presence of active genital infection.**
- **Previous Caesarean Section.**
- **Badly handled and referred cases.**

## METHODOLOGY

**Women fulfilling the above inclusion criteria are included in the study and explained about the study and its benefits and informed consent is obtained from the study group.**

## DEVICE PLACEMENT

**1**. Open the two-way tap and fold (fold should be so that the balloon is squeezed between the two wings of the device) to remove all air from it, close the two-way tap. The device is now completely deflated and ready for insertion. Patient should be in lithotomy position.

a. Sterile gel or cream is used and the device is folded (fold of the device should be in the vertical position or antero-posterior diameter of pelvis) and inserted in to the vagina below the fetal head, as shown in the diagram below.

b. Once inserted the device is placed like a posterior ventouse cup in the vagina as shown in the second diagram

***b. Insertion*** ***c. Device in position for inflation***

2. After insertion the patient is put back to supine position for the Caesarean Section. The distal end of the tubing with the attached syringe is held by an assistant.

3. Inflation should be carried out just before making the skin incision and exposing the lower segment. Inflate the device using 180mls of sterile saline with the syringe provided. The two-way tap should now be closed so that no fluid escapes.

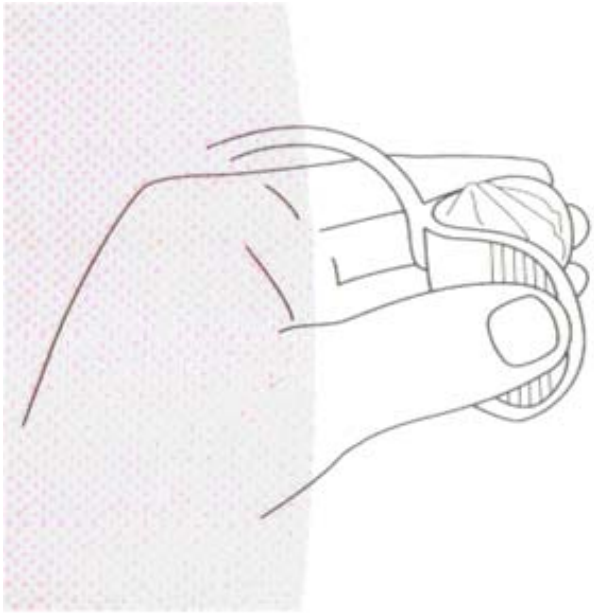
Uterine incision is made and delivery is performed as standard.

As soon as the baby is delivered, the device should be deflated by opening the two-way tap and aspirating saline with the syringe.

## DEVICE REMOVAL

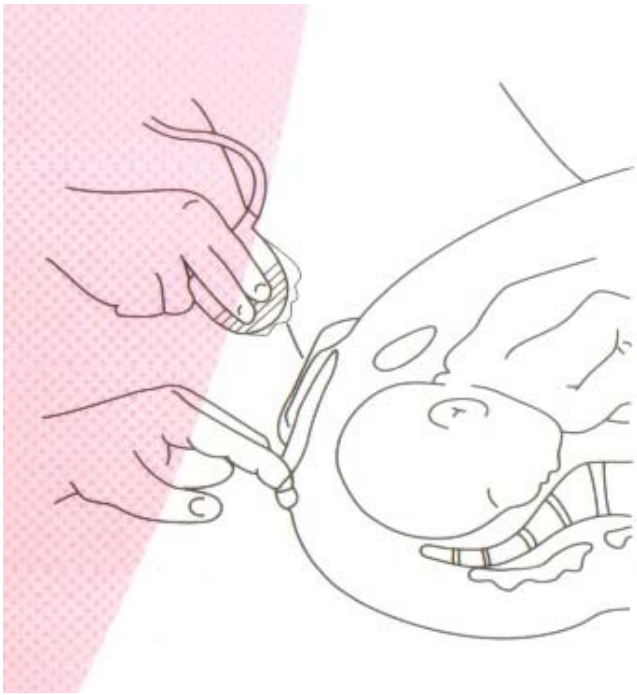
After completing the caesarean section, remove vaginally by gently pulling on the tubing or hooking index finger of one hand on the base plate.

# *Device Insertion*



The device is held by the wings between thumb and fingers and folded to squeeze the balloon between the two wings.

The tube attachment should be at the superior end as shown in the diagram.



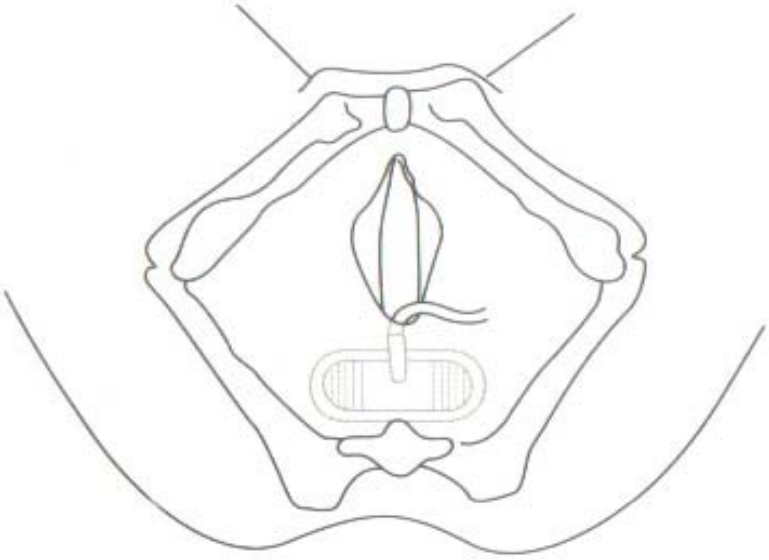
A liberal amount of obstetric cream should be used for insertion.

The process is very similar to inserting a silastic ventouse cup. Once inserted the device lies flat with the balloon surface in contact with the fetal head.

## *Device Placement*

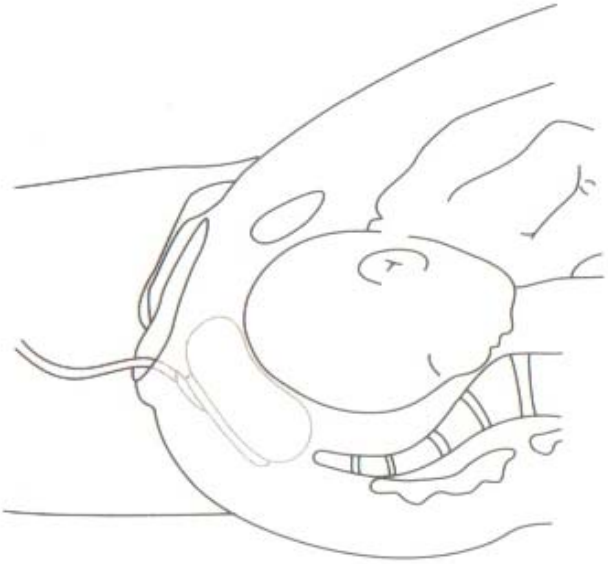
**DEVICE PLACEMENT**

The device should be pushed posteriorly towards the coccyx. Placement is similar to a posterior ventouse cup.



Position of the device seen after insertion and correct placement.

# *Device Inflation*



## DEVICE INFLATION

The patient's legs are now placed flat on the operating table before inflating the balloon.

Inflation should ideally be carried out after draping the patient for the Caesarean Section.

Use 150mls of Normal Saline with the 60mls syringe provided and close the tap so that no fluid escapes.

## RATIONALE FOR PERFORMING THE STUDY

Use of fetal pillow would make the delivery easier and reduce the complications associated in second stage CS and CS after a failed instrumental delivery .

# *Result and Analysis*

# 6 *Result and Analysis*

This study commenced with 30 women in each group who underwent second stage caesarean section. None of the patients in our study had epidural analgesia for pain relief in labor. In our study all the caesarean section were performed under spinal or epidural anesthesia by the consultant Obstetrician present in the labor ward.

Descriptive statistics were utilized and all results are presented as mean +/- SD and percentages. The Student 't-test' was used for quantitative comparative data were appropriate. Categorical Data were compared using Chi Square Test or Fischer's Exact Test if appropriate. Statistical significance was $p<0.05$.

# *Patient Characteristics*

## *1. Age Distribution*

**Table 1.**

| | Group | N | Mean | Std. Deviation | Std. Error Mean |
|---|---|---|---|---|---|
| **Age** | Device | 30 | 22.67 | 2.440 | 0.445 |
| | Control | 30 | 23.27 | 2.116 | 0.386 |

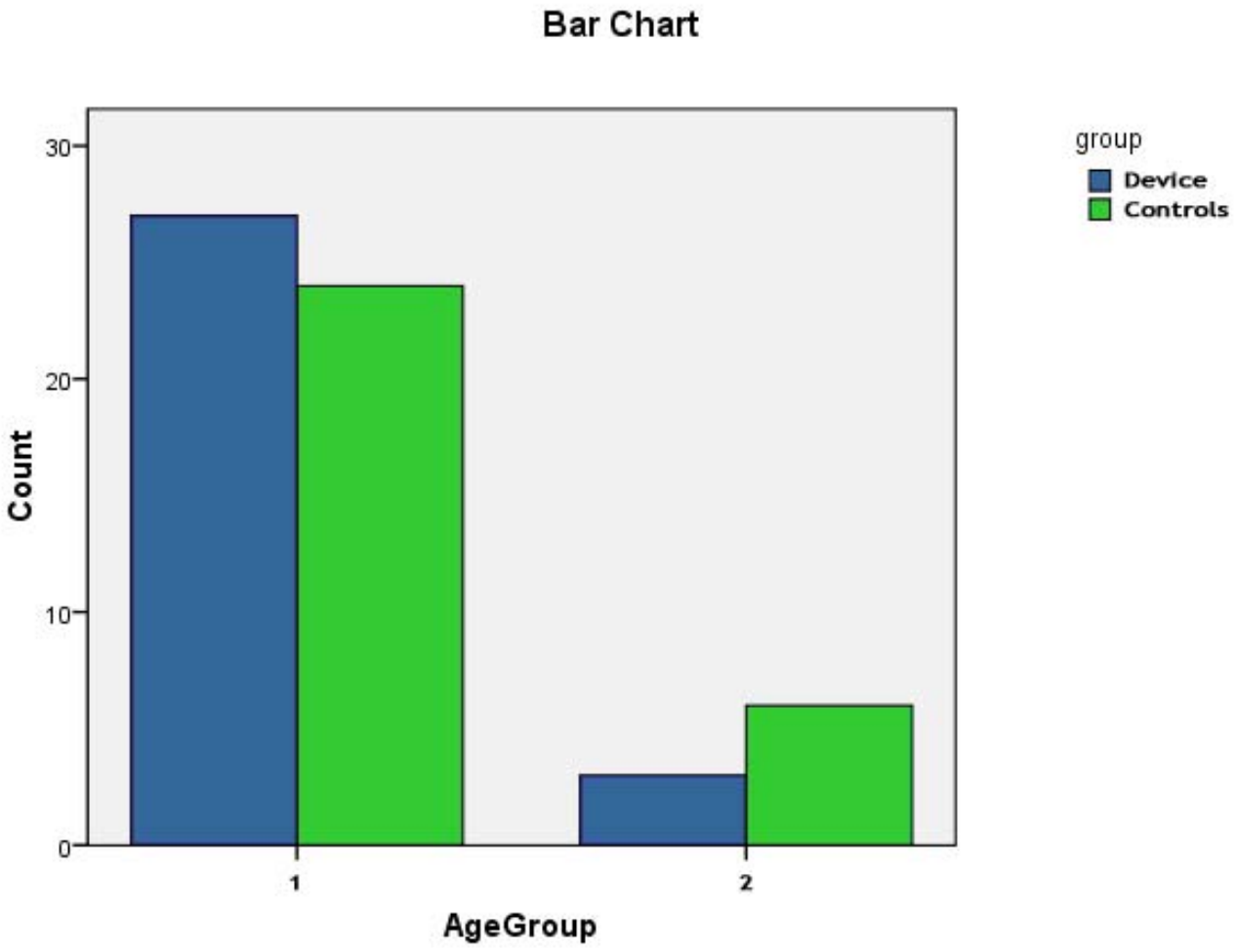
**p=0.313**

**Table 2.**

***Age Group * group***

| | | | Group | |
|---|---|---|---|---|
| | | **Group** | **Device** | **Control** |
| **Age (In Years)** | **20-25** | Count | 27 | 24 |
| | | % within group | 90.0% | 80.0% |
| | **26-30** | Count | 3 | 6 |
| | | % within group | 10.0% | 20.0% |

The mean age of the pregnant women was 22.67 yrs in the device group and 23.27 yrs in the control group. The distribution of women in the age group 20-25 yrs was relatively higher in both the groups (90% in device and 80% in control). The frequency of use of fetal pillow did not differ significantly p=0.313 with regard to the age group.



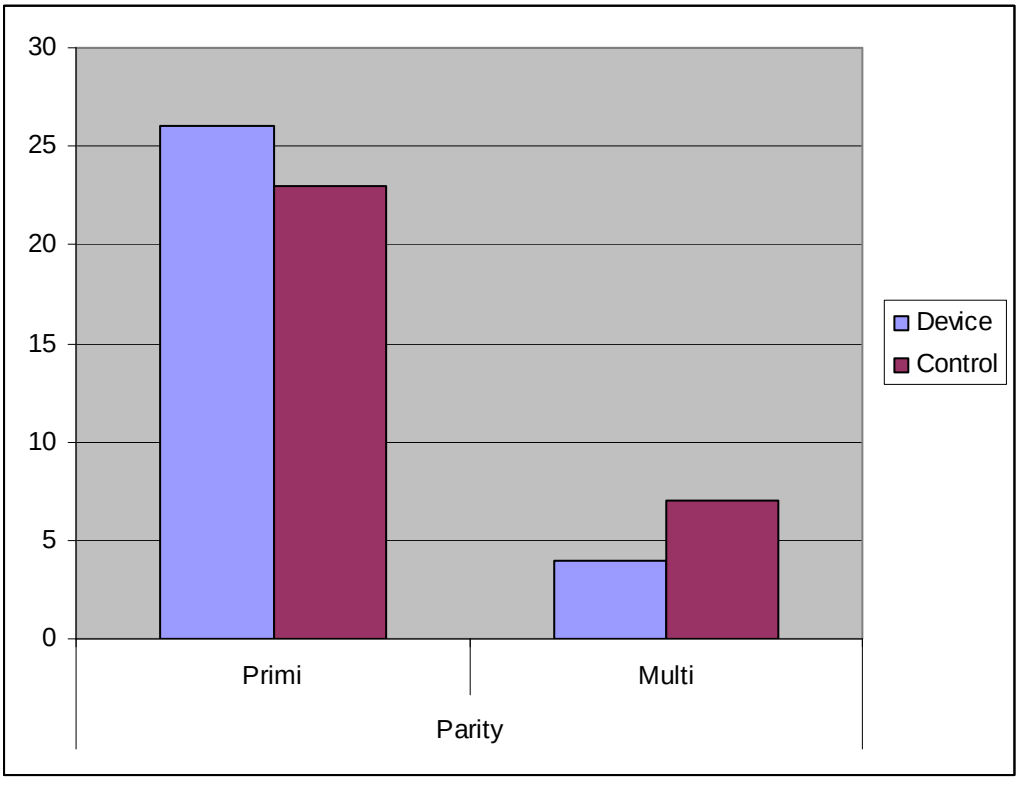
## *2. Parity*

**Table 3.**
**Parity * group**

| | | | Group | |
|---|---|---|---|---|
| | | | Device | Control |
| Parity | Primi | Count | 26 | 23 |
| | | % within group | 86.7% | 76.7% |
| | Multi | Count | 4 | 7 |
| | | % within group | 13.4% | 23.3% |

In the study group, 86.7% of women were Primi and 13.4% were Multigravida. In the control group 76.7% of women were Primi and 23.3% were Multigravida. This data shows more of Primigravida in both the groups ended up in second stage caesarean section when compared to multigravida.

The common indications were, cephalopelvic disproportion with fetal distress, secondary arrest of labor, failure of labor progress, deep transverse arrest.



# Group Statistics

**Table 4.**

**Parity * Time (Seconds)**

| | Parity | N | Mean | Std. Deviation | Std. Error Mean |
|---|---|---|---|---|---|
| Time (seconds) | Primi | 26 | 36.15 | 8.403 | 1.648 |
| | Multi | 4 | 42.50 | 8.660 | 4.330 |

**p=0.889 (p>0.05)**

**Table 5.**

**Parity * Blood Loss (ml)**

| | Parity | N | Mean | Std. Deviation | Std. Error Mean |
|---|---|---|---|---|---|
| Blood Loss (ml) | Primi | 26 | 681.92 | 176.114 | 34.539 |
| | Multi | 4 | 800.00 | 141.421 | 70.711 |

**p=0.508 (p>0.05)**

The analysis of variance (ANOVA) was applied to blood loss, Uterine incision to delivery interval time with regards to parity. It was found that these variables were not significant in the device group, implicating that the device used uniformly, whether primi or multigravida, reduced the blood loss and the operating time.

## *3. Duration of Second Stage of Labor (mins.)*

In the device group the duration of the second stage on an average was 75.67 mins. ( range 45 – 120 mins.).

# *Operative Characteristics*

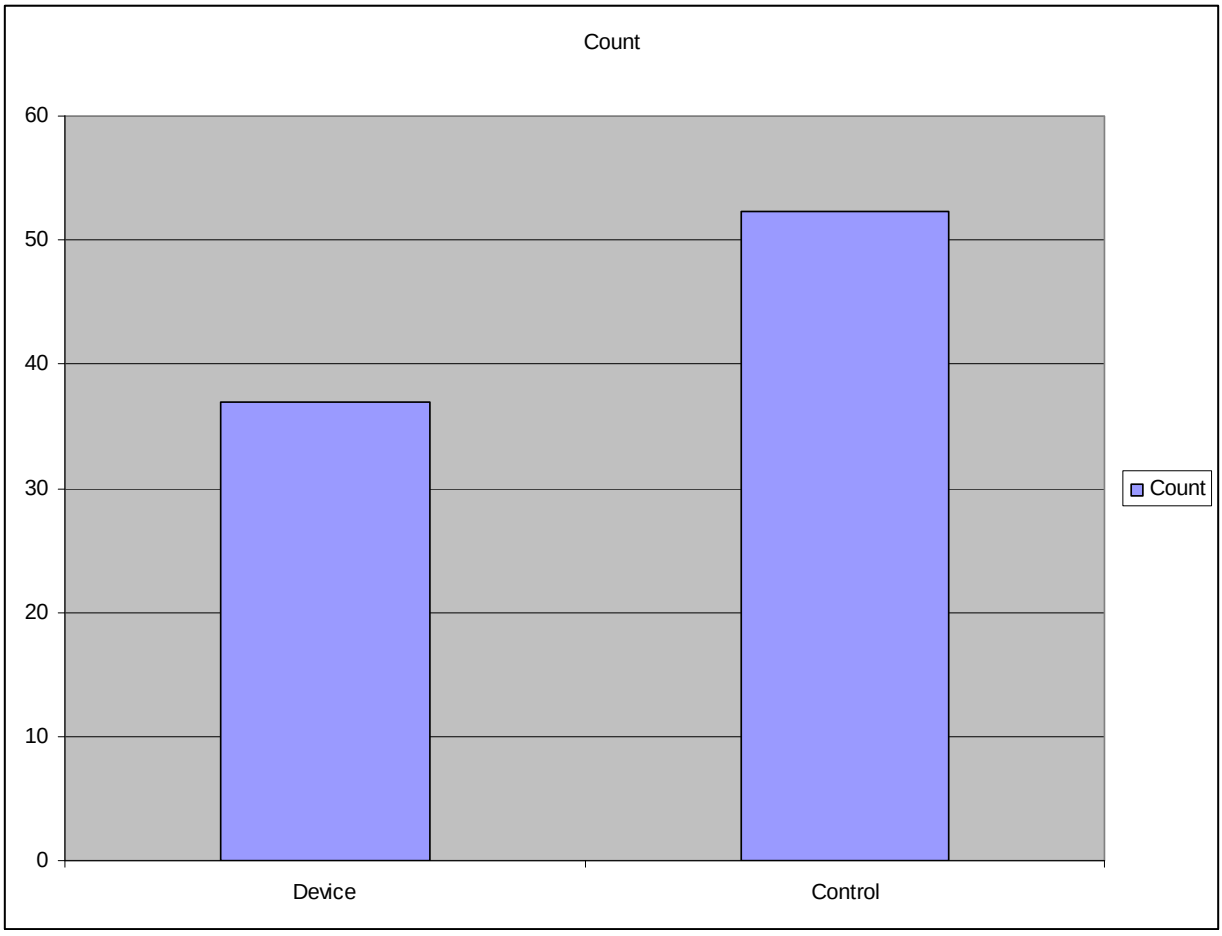
## *1. Uterine Incision to Delivery Interval (Seconds)*

**Table 6.**

| | group | N | Mean | Std. Deviation | Std. Error Mean |
|---|---|---|---|---|---|
| Time (seconds) | Device | 30 | 37.00 | 8.570 | 1.565 |
| | Control | 30 | 52.33 | 7.739 | 1.413 |

**p=0.000 (p<0.05)**

The mean Uterine incision to delivery interval in the device group was 37 sec. and in the control group was 52.33 sec. Hence the device disimpacted the deeply engaged head, thereby making the delivery of head easy and reducing the operating time significantly (p=0.000).

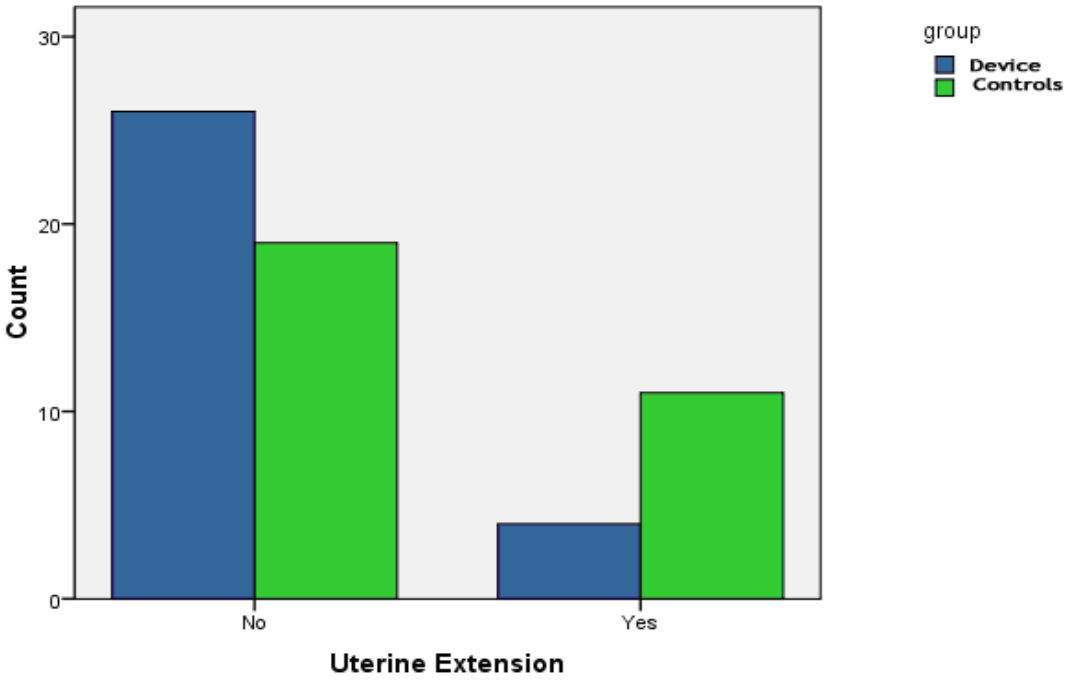


## *2. Uterine Incision Extension*

**Table 7. Uterine Externsion * Group**

| | | group | |
|---|---|---|---|
| | | Device | Control |
| Uterine Extension | No | 26 | 19 |
| | | 86.7% | 68.3% |
| | Yes | 4 | 11 |
| | | 13.3% | 31.7% |

p=0.037 (p<0.05)




In the device group, 26 patients (86.7%) had no extension of uterine incision.

Extension of Uterine incision was found in 4 patients (13.3%) in the device group as compared to 11 patients (31.7%) in the control group. Hence there is statistically significant reduction in the incidence of uterine incision extension (p=0.037) in the device group.

Among the four patients who had uterine incision extension three were non significant extension (defined as extension that does not increase the operating time) and one needed senior obstetricians help.

### *3. Blood Loss*

**Table 8.**

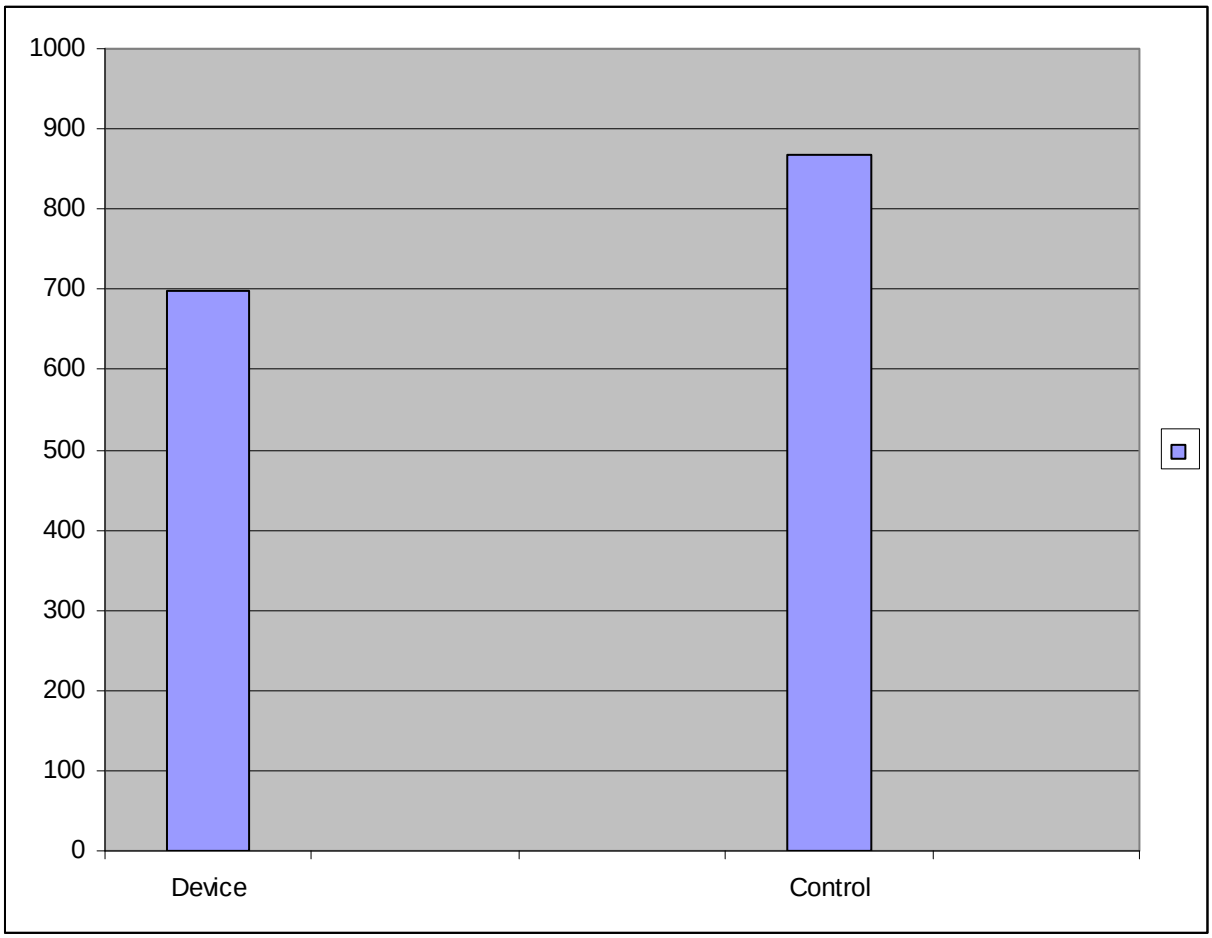
| | Group | N | Mean | Std. Deviation | Std. Error Mean |
|---|---|---|---|---|---|
| Blood Loss (ml) | Device | 30 | 697.67 | 174.567 | 31.871 |
| | Control | 30 | 868.33 | 131.623 | 24.031 |

**p=0.000 (p<0.05)**

The average blood loss in the device group was 697.67 ml ( Range 350 to 1000 ml) as compared to 868.33 ml (Range 650 – 1100 ml) in the control group. Significant reduction in blood loss in noted in the device group (p=0.000).

Statistically significant correlation was found in the device group between uterine incision to delivery time and blood loss (p=0.003).

No Blood transfusion was needed in the study group. In the control group four patients 13.3% required blood transfusion.

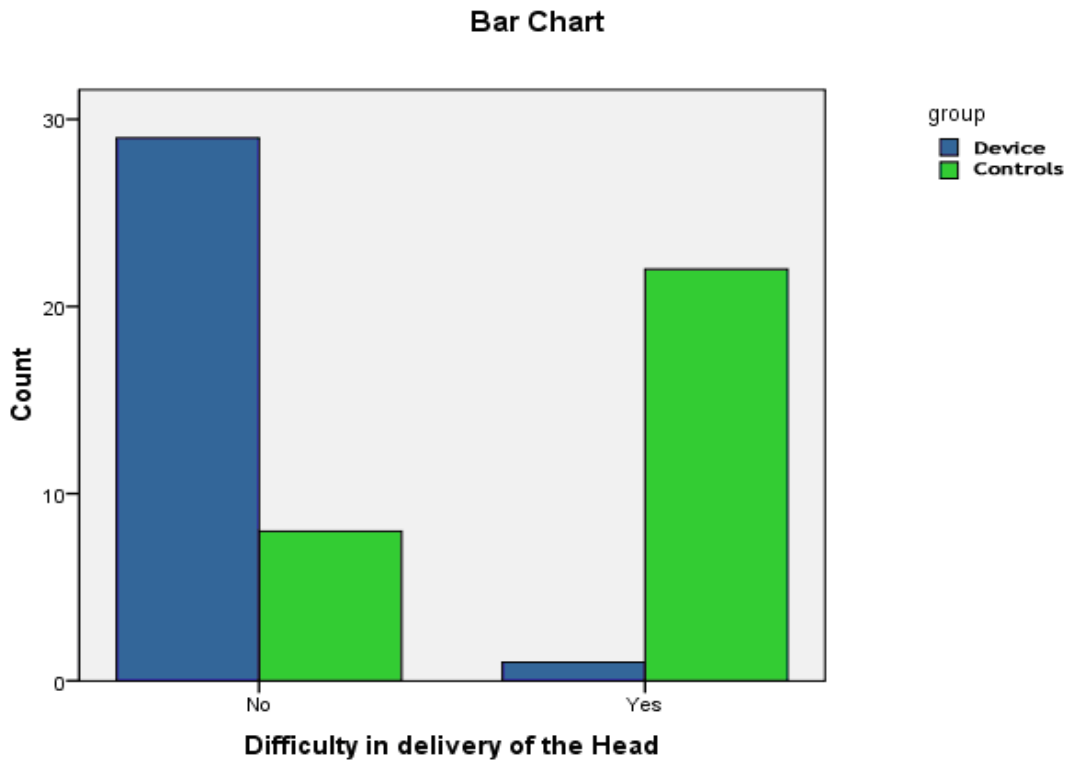



**Blood Loss**

## *4. Difficulty in Delivery of Head*

**Table 9.**

| | | | group | |
|---|---|---|---|---|
| | | | Device | Control |
| Difficulty in delivery of the Head | No | Count | 29 | 8 |
| | | % within group | 96.7% | 26.7% |
| | Yes | Count | 1 | 22 |
| | | % within group | 3.3% | 73.3% |




With the device use 96.7% of the cases, the surgeons reported easy delivery of the fetal head. They also found that the device was easy to insert. In the control group the surgeons described difficult delivery of fetal head in 22 cases.

## *5. Overall Satisfaction of Surgeons*

**Table 10.**

| | **Device Group** |
|---|---|
| **Satisfied** | **29** |
| | **96.7%** |
| **Not Satisfied** | **1** |
| | **3.3%** |

Overall satisfaction, among the surgeons, with the device use was 96.7%. The surgeons felt that on an average the elevation of the head intra operatively with the device use was two station above. At the time of insertion of the device the fetal head was non palpable abdominally in all the cases, the station was at the level of ischial spines in 17 cases, 1 cm below the ischial spine in 11 cases, 2 cm below the ischial spine in 2 cases.

### *6. Length of Hospital Stay*

**Table 11.**

| | Group | N | Mean | Std. Deviation | Std. Error Mean |
|---|---|---|---|---|---|
| Length of Hospital stay | Device | 30 | 7.00 | 0.000 | 0.000 |
| | Control | 30 | 7.53 | 0.937 | 0.171 |

**p=0.003 (p<0.05)**

The duration of hospital stay in the device group was 7 days, but in the control group the average duration was 7.53 days (Range 7-10 days). There is a significant reduction in the duration of hospital stay in the device group.

## *Neonatal Outcomes*

### *1. APGAR Score*

**Table 12.**

| | Group | N | Mean | Std. Deviation | Std. Error Mean |
|---|---|---|---|---|---|
| Apgar Score 1 min | Device | 30 | 6.67 | 1.093 | .200 |
| | Control | 30 | 6.10 | 1.029 | .188 |
| Apgar Score 5 mins. | Device | 30 | 7.93 | .740 | .135 |
| | Control | 30 | 7.27 | .907 | .166 |

In the APGAR score of the neonates delivered in the device group, both 1 min (6.67) and 5 mins (7.93), there exists elevation in the mean score which is statistically significant (for 1 min p=0.043, for 5 mins. p=0.003) as compared to the control group where the APGAR score 1 min (6.10) and 5 min (7.27). Hence by facilitating easy head delivery, good APGAR scores has been recorded in the device group. This reduces fetal morbidity.

### *2. Fetal Weight*

**Table 13.**

| | Group | N | Mean | Std. Deviation | Std. Error Mean |
|---|---|---|---|---|---|
| Weight of the Baby (kg) | Device | 30 | 2.859 | 1.2065 | .2203 |
| | Control | 30 | 3.290 | .2842 | .0519 |

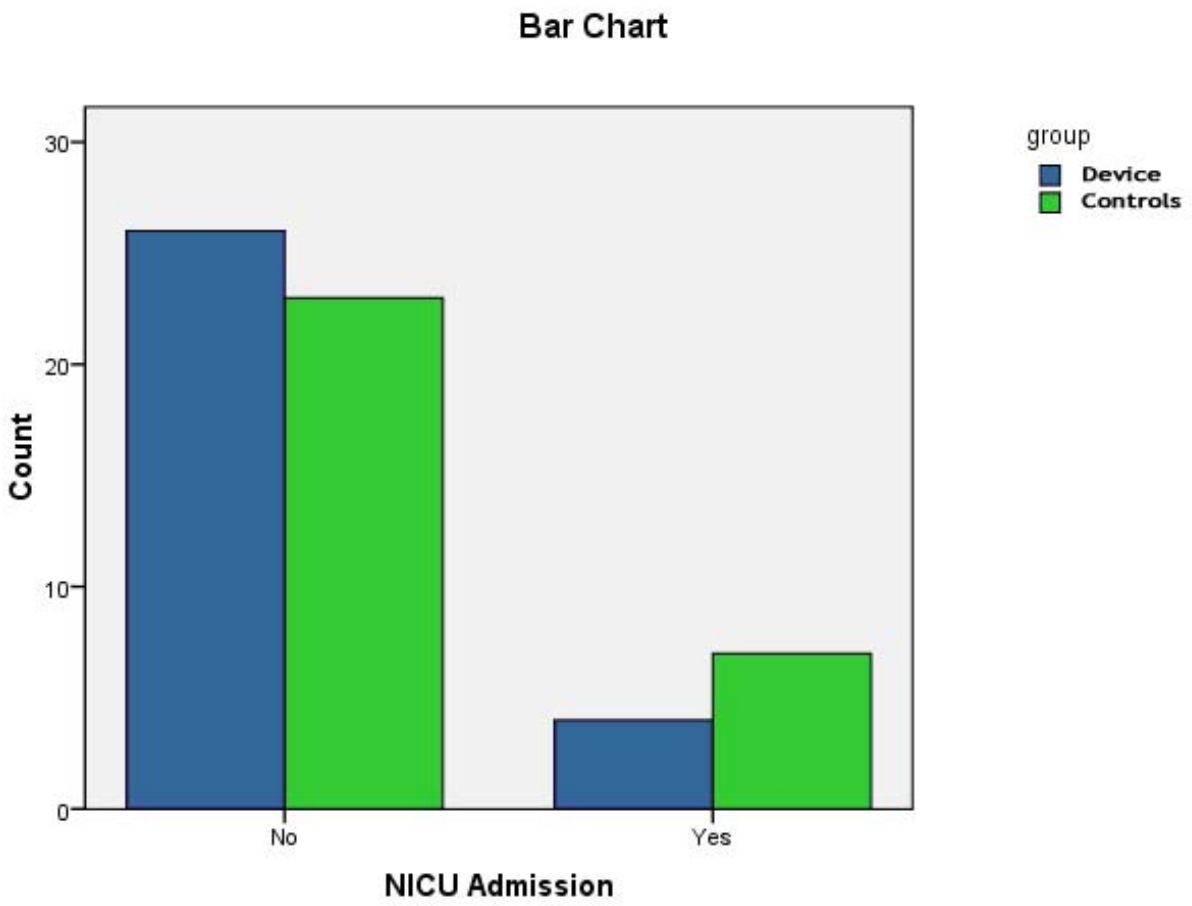
**p=0.062 (p>0.05)**

The average weight of the baby delivered in the study group was 2.859 Kg and in the control group was 3.290. There is no significant difference in the weight of the babies delivered in both the groups.

### *3. NICU Admission*

**Table 14. NICU Admission * Group**

| | | | Group | |
|---|---|---|---|---|
| | | | Device | Controls |
| NICU Admission | No | Count | 26 | 23 |
| | | % within group | 86.7% | 76.7% |
| | Yes | Count | 4 | 7 |
| | | % within group | 13.3% | 23.3% |



In the device group four babies 13.3% required NICU admission. The reason for admission were, one for non vigorous thick meconium and other three babies admitted for respiratory distress. The average duration NICU admission was 2 days. There was 100% no fetal trauma with the use of the device. In the control group, 7 babies – 23.3% required NICU admission for birth asphyxia, Low APGAR scores and Non vigorous maconium.

# *Discussion*

# 7 Discussion

**The background rate of second stage caesarean section has been estimated around 2% of all deliveries. Second stage caesarean section is a technically demanding and carries increased risk of maternal and neonatal morbidity.**

## *Parity*

In the present study, 86.7% of women who underwent second stage CS were PRIMI, this is similar to the study by Mandeep Singh et Al, reducing complications related to caesarean section in second stage using fetal disimpacting system – PRIMI 85.7%.

In their study, Shabla Baloch et Al, second stage interventions were more frequent among PRIMI gravida(45%).

The frequency of second stage interventions in the form of instrumental vaginal delivery and CS was found high in PRIMI gravidas which could be due to high rate of mismanagement and CPD, Rigid Perineum and Lack of Experience of previous labor in this group of women. Same was found in Feinstein et Al study who found nulliparity as a risk factor in second stage arrest and Al – Kadri H et Al who found nulliparous women having more chances of failed instrumental delivery.

## *Uterine Incision to Delivery Interval*

In the present study, the mean uterine incision to delivery interval in the device group was 37 seconds.

The median uterine incision to delivery interval in the device group was 66 seconds in their study by Mandeep Singh and R Varma in 2010 using the Fetal disimpacting system.

| Authors | Device Group | Control Group |
|---|---|---|
| **Mandeep Singh & R Varma** | **66 seconds** | **96 seconds** |

Seal et Al who studied outcome in seconds stage vs. first stage CS delivery found caesarean section performed in the second stage of labor had a longer incision delivery interval on an average 8.4 minutes.

Hence with the use of this simple device the incision delivery interval is shortened.

## *Uterine Incision Extension*

The incidence of uterine incision extension in second stage CS may be as high as 35%.

In our present study there was no extension of uterine incision in 86.7% of cases. This is similar to the study by Mandeep Singh and R Varma (2010) – in 24 patients (85.7%) there was no extension using the device.

In a study by Seema Chopra (2009), found extension of uterine incision occured in 22.8% of women undergoing second stage CS when the baby was delivered as cephalic when compared to reverse breech extraction.

Cebekulu and Buchmann (2006) – in their study found lower segment tears were noted in 31% of women undergoing CS in second stage of labor.

In our study, uterine incision extension was found in 13.3%. Hence with the device used when compared to the conventional techniques of head delivery, the incidence of uterine incision extension is much reduced.

## *Blood Loss*

In the present study, the average blood loss in the device group was 697.67 ml (Range 350 to 1000 ml). This is similar to the study by Mandeep Singh and R Varma (2010) – the mean blood loss during the CS with the device use was 700 ml (Range 300 to 1200 ml).

| Authors | Device Group | Control Group |
|---|---|---|
| **Mandeep Singh & R Varma** | **700 ml** | **1100 ml** |

In our study, none of the patient in the device group required blood transfusion but four patients 13.3% in the control group required blood transfusion.

In a study by Seal et Al (2010), blood transfusion in women undergoing CS in second stage was 4.83%.

Cebekulu and Buchmann (2006) reported in their study, 3 patients (7.6%) in women undergoing CS in second stage of labor required blood transfusion.

Hence this simple device used in our study, by reducing the uterine incision extension and reducing the mean blood loss, the need for blood transfusion is reduced, thereby the maternal morbidity is reduced.

## *Difficulty in Delivery of Head*

In the present study, 96.7% of the surgeons reported easy delivery of fetal head with the device use. In the control group the surgeons reported difficulty in delivery of the fetal head in 22 cases.

Cebekulu and Buchmann (2006) reported that in 12 of the cases (31%) who underwent second stage CS, surgeons described delivery of the fetal head as difficult.

In the study by Mandeep Singh and R Varma (2010) with Fetal Pillow, all the surgeons who used the device found the insertion easy and stated that the device facilitated the delivery. All surgeons stated that they would use it again and they would recommend it to another surgeon.

Hence this simple device by dislodging the wedged fetal head not only reduces maternal morbidity, also facilitates surgeon during surgery by avoiding the conventional techniques and its associated complications.

## *Length of Hospital Stay*

In various studies it has been quoted that duration of hospital stay for patients in second stage CS is increased.

In the present study the length of hospital stay in the device group was 7 days, as in our hospital patient is discharged only after suture removal on the seventh day. There is no increase in the duration of the hospital stay.

In the study Seal et Al, the mean length of stay in the hospital after delivery was higher in second stage CS (Avg. 6.4 day vs. 5.2 days).

Cebekulu and Buchmann, the median hospital stay for women in caesarean section in second stage was 2 days (Avg. 2 – 6 days).

## *APGAR Score*

In the present study 5 min APGAR score in the device group was 7/10 and above in 29 patients (96.6%).

Cebekulu and Buchmann study showed 5 mins. APGAR score below 7 were found in 18% after Second Stage CS.

Seal et Al, study showed 5 mins. APGAR score 3 or less in 3.26% as compared 0.29% in first stage CS.

Hence with the device use the Fetal head is elevated, so less manipulation with head delivery resulting in good 5 mins. APGAR scores. There was no fetal trauma found with the device use.

## *NICU Admission*

In the present study there was 13.3% NICU admissions with no neonatal death.

Cebekulu and Buchmann study showed 17 babies (44% ) born out of second stage CS required admission to the neonatal unit as compared to 3 babies (8%) of the controls.

Seal et Al in their study showed 9.68% of the neonates delivered by second stage CS required NICU admission for more than 24 hours.

Hence with the device use there is reduction in the NICU admission rate.

# *Summary*

# 8 Summary

In this study, an atraumatic device **FETAL PILLOW** was evaluated in 30 patients who underwent second stage caesarean section during the study period 2010 – 2011 and were simultaneously compared with those patients who underwent second stage CS without Fetal Pillow at ISO KGH Hospital for Women and Children, Triplicane, Chennai.

The mean age group of the studied women was 22.67 years. The distribution of the women in the age group 22-25 years was relatively higher.

Among the studied women, 86.7% were PRIMI gravida.

The mean duration of the second stage of the labor in the study group was 75.67 minutes.

With the use of Fetal Pillow, there was significant reduction (p=0.000) in the uterine incision to delivery interval time – 37 seconds as compared to 52.33 seconds in the control group.

When the uterine incision extension was compared, there was significant reduction in its incidence in the study group (13.3%) as compared to their control group (31.7%).

With regards to the blood loss, the average blood loss in the device group was 697.67ml, with no patients requiring blood transfusion. but in the control group, the blood loss was 868.33ml and four patients required blood transfusion.

There was no increase in the duration of hospital stay in the study group (7 days). But in the control group the mean duration was increased (7.53 days).

Average weight of the baby delivered in the study group was 2.859 Kg. Good 5mins. APGAR Scores were recorded in the device group which was attributed to easy head delivery and less manipulation.

There was no maternal and fetal trauma attributable to the device use.

**Surgeons review:**

The Surgeons experience was graded on a scale of 1-5 ( 1 – Very difficult and 5- Very Easy) regarding the ease of delivery. Surgeons reported easy delivery of the fetal head during surgery (96.7%). Also, they found that the device was easy to insert and remove.

.

# *Conclusion*

# 9 *Conclusion*

**Fetal Pillow** seems to be effective in reducing some of the problems associated with the caesarean section in the second stage of labor – both maternal and fetal morbidity is reduced.

- There was significant reduction in the extension of the uterine incision.
- There was significant reduction in the mean blood loss.
- The operative time was reduced.
- The Blood Transfusion was avoided.
- There was no maternal and fetal trauma attributable to the device use.

Hence, this simple atraumatic device, Fetal Pillow, seems to facilitate the delivery of the impacted fetal head during caesarean section at full dilatation. This device reduces the extension of Uterine Incision, Blood Loss, Operative Time and Fetal Morbidity.

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# 10 *Bibliography*

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# *Annexures*

# 11 Annexures

## PROFOMA
### FETAL PILLOW STUDY

**RANDOMISATION** **FP** **NO FP**

Date of delivery EDD

Trial No Center No

Age Parity

Gestation Maternal weight

Previous Deliveries

**Labour data**

Length of 1st Stage Length of II stage

Augmentation with Oxytocin Y/ N

Abdominal Palpation (Head palpable) Pre insertion 0/5 1/5

Position of Occiput: Anterior / Posterior/ Transverse

Station of head -1 / 0 / +1 / +2

Caput: None, Mild, Moderate, Severe

**Instrument Use**

Indication for instrumental delivery

None / Forceps / Ventouse / Sequential

Number of pulls <3, >3

Insertion of FP (1 Very difficult, 2 difficult, 3 not difficult, 4 easy, 5 very easy) ☐

**VOLUME OF FLUID INJECTED 180 mls**

LSCS Time to complete ☐ GA ☐ Spinal/Epidural ☐

Uterine incision Delivery time in seconds _____

Delivery of fetal head
(1 Very difficult, 2 difficult, 3 not difficult, 4 easy, 5 very easy) ☐

Blood Loss ☐ Fetal weight _____

Incision extension: Y/ N

If Yes

Non significant extension (defined as
an extension that does not increase operating time) ☐

Significant Extension

Increase in operating time ☐

Cause of post partum hemorrhage ☐

Need for senior help ☐

Involvement of Cervix, Vagina, Bladder ☐

APGAR scores 1min 5min 10min

Hb Pre op Post op

Cord pH ☐

Device removal (Easy/ Difficult)

Length of Hospital Stay ☐

Need for Blood transfusion ☐

Baby stay in days Neonatal Intensive Care Unit ☐

# *Master Chart*

| | | | | | | | Cases - Device Group | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Station of the Head | Station of the Head | | | | | | | | | | | | |
| IP No. | Name | Age | Parity | Level Pre Op | Level Intra Op | Weight of the Baby (kg) | Time (seconds) | Blood Loss (ml) | Uterine Extension | Difficulty in delivery of the Head | Overall Satisfaction | Apgar Score | Apgar Score | NICU Admission | Length of Hospital stay | Duration of Second Stage | Blood Transfusion |
| 22545 | Prashathi | 20 | 1 | 0 | -3 | 2.5 | 35 | 700 | No | No | Good | 7 . /10 | 8 . /10 | No | 7 | 65mins | No |
| 22682 | Selvi Saravanan | 23 | 1 | 0 | -3 | 4.1 | 35 | 1000 | No | No | Good | 4 . /10 | 6 . /10 | Yes | 7 | 120mins | No |
| 23000 | Muthu Lakshmi | 20 | 1 | 1 | -3 | 3.06 | 35 | 700 | No | No | Good | 7 . /10 | 8 . /10 | No | 7 | 90mins | No |
| 23868 | Mohana Krishni | 20 | 1 | 1 | -3 | 3.6 | 45 | 800 | No | No | Good | 6 . /10 | 8 . /10 | No | 7 | 85mins | No |
| 586 | Shreema | 22 | 1 | 0 | -3 | 3.295 | 45 | 700 | No | No | Good | 8 . /10 | 9 . /10 | No | 7 | 100mins | No |
| 2230 | Lakshmi | 22 | 1 | 1 | -3 | 2.7 | 40 | 750 | No | No | Good | 8 . /10 | 9 . /10 | No | 7 | 80mins | No |
| 2895 | Suji | 20 | 1 | 1 | -3 | 2.5 | 45 | 850 | No | No | Good | 6 . /10 | 8 . /10 | No | 7 | 70mins | No |
| 3856 | Varalakshmi | 24 | 2 | 0 | -2 | 3.39 | 45 | 700 | No | No | Good | 7 . /10 | 8 . /10 | No | 7 | 80mins | No |
| 3899 | Akila | 20 | 1 | 0 | -3 | 2.695 | 40 | 750 | No | No | Good | 6 . /10 | 7 . /10 | No | 7 | 75mins | No |
| 4580 | Kala | 24 | 3 | 0 | -3 | 3.155 | 45 | 700 | No | No | Good | 5 . /10 | 7 . /10 | No | 7 | 60mins | No |
| 18479 | Ramya | 21 | 1 | 0 | -3 | 2.97 | 40 | 700 | No | No | Good | 8 . /10 | 9 . /10 | No | 7 | 45mins | No |
| 18690 | Ruma Biswas | 22 | 1 | 2 | -1 | 2 | 30 | 780 | No | No | Good | 7 . /10 | 8 . /10 | No | 7 | 90mins | No |
| 18787 | Devi | 24 | 1 | 0 | -3 | 2.84 | 30 | 750 | No | No | Good | 7 . /10 | 8 . /10 | No | 7 | 70mins | No |
| 19383 | Kalaivani | 24 | 1 | 1 | 0 | 3.8 | 40 | 700 | No | No | Good | 6 . /10 | 7 . /10 | No | 7 | 60mins | No |
| 20878 | Mahalakshmi | 20 | 1 | 1 | -2 | 3.11 | 30 | 600 | No | No | Good | 7 . /10 | 8 . /10 | No | 7 | 100mins | No |
| 21134 | Jotheeswari | 24 | 3 | 0 | 3 | 3 | 30 | 800 | No | No | Good | 7 . /10 | 8 . /10 | No | 7 | 75mins | No |
| 21651 | Devi | 21 | 1 | 0 | 3 | 2.675 | 45 | 700 | No | No | Good | 7 . /10 | 8 . /10 | No | 7 | 60mins | No |
| 21866 | Esther Mary | 25 | 1 | 0 | 2 | 3.07 | 50 | 900 | Yes | No | Good | 7 . /10 | 8 . /10 | Yes | 7 | 80mins | No |
| 22127 | Premavathy | 28 | 1 | 0 | Breech | 2.9 | 50 | 1000 | No | Yes | Not Satisfied | 7 . /10 | 8 . /10 | Yes | 7 | 65mins | No |
| 22178 | Jeenath Nisha | 21 | 1 | 0 | 3 | 3.21 | 40 | 800 | No | No | Good | 6 . /10 | 7 . /10 | Yes | 7 | 120mins | No |
| 6770 | Seetha | 25 | 2 | 0 | -2 | -3.09 | 50 | 1000 | Yes | No | Good | 7 . /10 | 8 . /10 | No | 7 | 45mins | No |
| 8074 | Chitra | 22 | 1 | 1 | -3 | 2.75 | 35 | 600 | No | No | Good | 7 . /10 | 8 . /10 | No | 7 | 90mins | No |
| 10569 | Meena | 22 | 1 | 1 | -1 | 2.7 | 30 | 800 | No | No | Good | 7 . /10 | 8 . /10 | No | 7 | 60mins | No |
| 10782 | Mercy Patricia | 23 | 1 | 0 | -2 | 2.58 | 20 | 600 | No | No | Good | 7 . /10 | 8 . /10 | No | 7 | 70mins | No |
| 11860 | Deviga | 29 | 1 | 0 | -2 | 3.11 | 30 | 500 | No | No | Good | 8 . /10 | 9 . /10 | No | 7 | 60mins | No |
| 12238 | Leela | 21 | 1 | 1 | -1 | 3.56 | 30 | 450 | No | No | Good | 6 . /10 | 8 . /10 | No | 7 | 45mins | No |
| 12303 | Nadhiya | 24 | 1 | 1 | -1 | 3.3 | 30 | 400 | No | No | Good | 8 . /10 | 9 . /10 | No | 7 | 60mins | No |
| 13005 | Sakthi Priya | 24 | 1 | 2 | 0 | 3.3 | 35 | 400 | Yes | No | Good | 4 . /10 | 7 . /10 | No | 7 | 75mins | No |
| 13265 | Nandhini | 26 | 1 | 1 | -2 | 3.6 | 40 | 350 | No | No | Good | 8 . /10 | 9 . /10 | No | 7 | 85mins | No |
| 13669 | Geetha | 20 | 1 | 0 | -2 | 3.4 | 15 | 450 | Yes | No | Good | 5 . /10 | 7 . /10 | No | 7 | 90mins | No |

## Control Group

| IP No. | Name | Age | Parity | Station of the Head | Weight of the Baby (kg) | Time (seconds) | Blood Loss (ml) | Uterine Extension | Difficulty in delivery of the Head | Apgar Score | Apgar Score | NICU Admission | Length of Hospital stay | Blood Transfusion |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 18471 | Sangu Lakshmi | 22 | 1 | 0 | 3.63 | 60 | 1000 | Yes | Yes | 5 . /10 | 6 . /10 | yes | 9 | Yes |
| 18498 | Poornima | 24 | 2 | -1 | 3.45 | 40 | 800 | No | No | 6 . /10 | 7 . /10 | no | 7 | No |
| 18808 | Vimala | 22 | 1 | 1 | 3.495 | 45 | 700 | No | Yes | 7 . /10 | 8 . /10 | no | 7 | No |
| 19014 | Salma | 26 | 2 | -1 | 3 | 50 | 800 | No | No | 6. /10 | 7 . /10 | no | 7 | No |
| 19188 | Yasmin | 23 | 2 | 0 | 3.42 | 50 | 700 | No | Yes | 8 . /10 | 9 . /10 | no | 7 | No |
| 19682 | Sangeetha | 21 | 1 | 1 | 3.19 | 45 | 950 | Yes | Yes | 6 . /10 | 7 . /10 | Yes | 7 | No |
| 19849 | Kanchana | 26 | 3 | 1 | 3.64 | 45 | 1050 | Yes | Yes | 5 . /10 | 6 . /10 | No | 8 | Yes |
| 20645 | Dorathy | 24 | 1 | 2 | 3.57 | 50 | 700 | No | Yes | 7 . /10 | 8 . /10 | No | 7 | No |
| 20824 | Afrin | 22 | 1 | 1 | 3.69 | 40 | 750 | No | Yes | 6 . /10 | 7. /10 | No | 7 | No |
| 21003 | Banu Priya | 23 | 1 | 1 | 2.905 | 55 | 700 | Yes | No | 7 . /10 | 8 . /10 | No | 7 | No |
| 21405 | Saranya | 23 | 1 | 1 | 3.52 | 60 | 1000 | No | Yes | 6 . /10 | 7 . /10 | No | 7 | No |
| 21566 | Neelavathy | 22 | 2 | -1 | 3.7 | 55 | 650 | No | No | 7 . /10 | 8 . /10 | No | 7 | No |
| 22154 | Malathy | 21 | 1 | 1 | 3.6 | 50 | 800 | No | Yes | 7 . /10 | 8 . /10 | No | 7 | No |
| 22516 | Kamatchi | 20 | 1 | 1 | 3.4 | 45 | 750 | No | Yes | 5 . /10 | 7 . /10 | No | 7 | No |
| 22610 | Renuka Devi | 22 | 1 | 0 | 3.04 | 65 | 950 | Yes | Yes | 5 . /10 | 7 . /10 | Yes | 9 | No |
| 22953 | Kamatchi | 28 | 6 | 1 | 3.75 | 40 | 850 | No | Yes | 6 . /10 | 7 . /10 | No | 7 | No |
| 65 | Suriya | 24 | 1 | 2 | 3.37 | 55 | 700 | No | No | 7. /10 | 8 . /10 | No | 7 | No |
| 185 | Maha Lakshmi | 26 | 1 | 0 | 3.115 | 65 | 1100 | Yes | Yes | 5 . /10 | 6 . /10 | No | 8 | Yes |
| 4943 | Parimala | 25 | 1 | 1 | 3.25 | 50 | 800 | No | Yes | 6 . /10 | 7 . /10 | No | 7 | No |
| 4841 | Anjalai | 27 | 1 | 0 | 2.69 | 60 | 1000 | Yes | Yes | 5 . /10 | 6 . /10 | Yes | 10 | No |
| 4874 | Flora | 22 | 1 | 0 | 3.1 | 60 | 1000 | Yes | Yes | 6 . /10 | 8 . /10 | No | 8 | No |
| 4771 | Kalaivani | 22 | 1 | -1 | 3.285 | 50 | 800 | No | No | 8 . /10 | 9 . /10 | No | 7 | No |
| 8605 | Chitra | 26 | 1 | 1 | 3 | 55 | 900 | No | No | 7 . /10 | 8 . /10 | No | 7 | No |
| 8322 | Suganya | 24 | 1 | 1 | 3.001 | 40 | 950 | Yes | Yes | 5 . /10 | 7 . /10 | Yes | 8 | No |
| 8688 | Samundeeswari | 20 | 1 | 1 | 2.9 | 60 | 900 | No | Yes | 6 . /10 | 7 . /10 | No | 7 | No |
| 8935 | Yamuna | 21 | 2 | 1 | 3.1 | 65 | 950 | No | Yes | 6 . /10 | 7 . /10 | No | 7 | No |
| 9048 | Girija | 21 | 1 | 2 | 3 | 55 | 900 | No | Yes | 6 . /10 | 7 . /10 | No | 7 | No |
| 9189 | Kokila Priya | 25 | 1 | 0 | 3.2 | 60 | 1000 | Yes | Yes | 4 . /10 | 6 . /10 | Yes | 10 | No |
| 9087 | Supriya | 24 | 1 | 0 | 3.5 | 50 | 800 | No | No | 8 . /10 | 9 . /10 | No | 7 | No |
| 9294 | Vinodha | 22 | 1 | 1 | 3.2 | 50 | 1100 | Yes | Yes | 5 . /10 | 6 . /10 | Yes | 9 | Yes |